### IN THE UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster

#### This document relates to:

The County of Cuyahoga v. Purdue Pharma L.P., et al., Case No. 17-OP-45004

The County of Summit, Ohio, et al. v. Purdue Pharma L.P. et al., Case No. 18-OP-45090

> REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE DAVID CUTLER'S OPINIONS AND PROPOSED TESTIMONY

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Plaintiffs' response to the Cutler Daubert motion ignores the most fundamental flaws in Cutler's analyses. In their motion, Defendants argued that Cutler's analyses are both unreliable and completely untethered to Plaintiffs' legal theory. Yet, Plaintiffs ignore that Cutler did not measure the relationship (if any) between opioid shipments to the Track One Counties and Plaintiffs' alleged harms. Indeed, Cutler cannot say if any of the increases in average mortality across a 400-county sample that he blames on prescription opioid shipments involve individuals who ever received a prescription for opioids marketed or distributed by Defendants, let alone that the 400-county average applies to the Track One Counties. Instead, Cutler merely assumes without any stated support that the average correlation between shipments of all prescription opioids to these 400 counties and all opioid mortality relates to Defendants and holds in the Track One Counties. Nor does Cutler make any effort to tie any alleged misconduct by any or all of the Defendants to any medically unnecessary opioid shipments to the Track One Counties which, in turn, harmed Plaintiffs. Using all shipments as the starting point of his direct regression, Cutler cannot and does not isolate alleged harms caused by shipments that should have been blocked or were solely the result of improper marketing, as opposed to shipments for legitimate medical need.

In short, Cutler measures the wrong relationship. At most, Cutler's analyses might allow him to opine that in an average county (not the Track One Counties), more shipments by Defendants and non-defendants of medicines with FDA-approved black box warnings of the risk of abuse, addiction, and death, are correlated with more opioid-related deaths. That opinion is not relevant. Because Cutler is unable to decouple lawful from unlawful conduct, or distinguish the effect of shipments by Defendants versus others, Cutler cannot opine that there is a causal relationship between any alleged wrongdoing and any alleged harm in the Track One Counties.

Plaintiffs also do not so much as acknowledge the layered nature of Cutler's opinions. Even if the Court found that each step in Cutler's analysis satisfied Rule 702 (and they do not), Cutler's multiplication of a variety of aggregate, national-level estimates to attribute complex, multi-faceted societal harms in the Track One Counties to alleged Defendant misconduct is both unprecedented and unreliable. (Opening Br. at 1, 8). His opinions should be excluded.

#### I. <u>ARGUMENT</u>

Plaintiffs' response to the Cutler *Daubert* motion addresses Cutler's qualifications (which are not at issue), and how Cutler's analyses purportedly fit into Plaintiffs' overall damages computations. These issues are irrelevant. Cutler's opinions should be excluded because they do not fit the case, are irrelevant and unreliable, and because Cutler's models suffer from serious methodological flaws. Nothing in Plaintiffs' response shows otherwise.

# A. Cutler's Opinions Are Irrelevant and Unreliable Because He Did Not Measure the Relationship Between the Alleged Wrongdoing and the Alleged Harm.

Cutler's opinions are irrelevant and unreliable for two key reasons: (1) Cutler's indirect model impermissibly assumes the very connection he purports to prove; and (2) Cutler's direct model is untethered to Plaintiffs' legal theory and alleged injury.

#### 1. Cutler's Indirect Model Presupposes What It Purports To Prove.

It is hornbook law that an expert cannot "assume[] as truth the very issue that [the plaintiff] needs to prove in order to recover." *Clark v. Takata Corp.*, 192 F.3d 750, 757 (7th Cir. 1999). Yet, Plaintiffs do not dispute that Cutler's indirect model—which is used to calculate the majority of Plaintiffs' alleged damages—assumes that Defendants are to blame for opioid-related mortality he cannot explain. (Opening Br. at 5, 16). Indeed, shipments are not even an independent variable in the indirect model; Cutler designed the model to simply assume that

otherwise unexplained harms are attributable to prescription opioid shipments. That, of course, means that his indirect model cannot reliably demonstrate causation.

2. Cutler's Direct Model Is Untethered To Plaintiffs' Legal Theory.

Plaintiffs do not dispute that Courts routinely exclude causation experts who, like Cutler, offer opinions that fail to connect the alleged wrongdoing to the alleged harm. (*See* Opening Br. at 3–4). Nor do they dispute two fundamental points:

- Cutler "can't say whether any of the increase in mortality [i.e., the harms] that [he] attribute[s] to defendants resulted from individuals who actually got a prescription for one of the opioids that was manufactured or distributed by any defendant," and
- Cutler "makes no effort to disentangle the effect of Defendants' conduct from that of non-defendants." (Opening Br. at 4–5).

Nevertheless, Plaintiffs argue that "evaluating the effect of Defendant misconduct is an *explicit* step in Prof. Cutler's analysis." (Response at 20). That is simply not true. Plaintiffs also argue that Cutler "need not link particular shipments … to particular harms." (Response at 20). Plaintiffs may not need to link particular shipments to particular harms, but they certainly must link shipments by Defendants to the Track One Counties and show that *those shipments* caused Plaintiffs' alleged injury. As discussed below, Cutler's models do not do that.

First, Plaintiffs do not dispute that Cutler's direct regression model analyzes only the relationship between (i) all prescription opioid shipments from both Defendants and non-defendants—whether allegedly caused by misconduct or not—in 400 counties across the country and (ii) all opioid mortality (both prescription and illegal) in those counties. (Opening Br. at 5). Cutler never ran a regression that analyzed the relationship (if any) between shipments caused by Defendants' alleged wrongdoing and opioid mortality (or any other harms). (Id. at 16 (claiming Cutler opines only on "the relationship between opioid-related mortality and opioid shipments")). Instead, Cutler's analyses rely on the "average impact" he estimates based on the

alleged relationship between *all* prescription opioid shipments and all mortality in 400 counties across the country. (Opening Br. at 5-6). Cutler's direct model cannot isolate the extent to which Defendants allegedly unlawful conduct caused opioid-related harms in the two Track One Counties because it does not even purport to analyze shipments to Summit and Cuyahoga Counties, let alone the extent to which the shipments are attributable to Defendants' conduct as opposed to that of non-parties. (Opening Br. at 5, 16).

Cutler's "step three"—which Plaintiffs apparently claim is the "explicit step"—does not link harms to alleged misconduct, either. Cutler simply multiplied his "average impact" of *all shipments* by percentages of prescriptions provided by Rosenthal (for Manufacturer Defendants), and stated he could do the same with percentages of shipments supplied to him by Plaintiffs' counsel (for Distributor Defendants). (Response at 20–22). Plaintiffs do not even try to explain how Cutler could estimate harm resulting solely from shipments caused by Defendants' alleged misconduct merely by multiplying the percentages calculated by Rosenthal and counsel by his "average impact." Plaintiffs concede that none of their experts analyzed the alleged relationship between shipments caused by misconduct of Defendants and any harms. (Response at 4 ("Rosenthal did not compute harms")). But even if Rosenthal's model and counsel's numbers were capable of isolating the percentage of Defendants' misconduct (they are not), Cutler's direct model is still only capable of applying those percentages to his calculation of the average impact of *all* shipments across 400 different counties—*not* the average impact of shipments resulting from misconduct in the Track One Counties.

That Cutler does not analyze the relationship between alleged wrongdoing and harms is perhaps best reflected in his claim that he can insert *any* percentage of "shipments attributable to the defendants' misconduct" in his model (without re-running his regression) and estimate

the percentage of harm caused by that unique percent of shipments. (Response at 22). In other words, alleged misconduct has no place in Cutler's model because Cutler's "average impact" would stay the same regardless of whether the percentage of shipments allegedly caused by Defendant wrongdoing was 0%, 1%, or 100%. The absurdity of this opinion confirms that Cutler himself did nothing to analyze the relationship between alleged misconduct and harms.

Because Cutler did not estimate the relationship between shipments allegedly caused by misconduct and harms, Cutler's direct model implicitly assumes—without any justification that every single MME<sup>1</sup> shipped across the country contributed to mortality from both prescription opioids and illegal drugs in a uniform, "average" way, if at all. Indeed, he must, because he makes no effort to separate the contribution to the "average" impact of shipments by Defendants and non-Defendants, or to distinguish between shipments not caused by any wrongdoing and shipments allegedly caused by wrongdoing. For that reason alone, his opinions should be excluded. See, e.g., Multimatic, Inc. v. Faurecia Interior Sys. USA, Inc., 358 F. App'x 643, 654 (6th Cir. 2009) (affirming exclusion of expert because "[e]xperts may not assume facts without some support for those assumptions in their expert report or elsewhere in the record"); In re Worldcom, Inc., 371 Br.R.33, 41 (Bankr. S.D.N.Y. 2007) citing Eastern Auto Distributors, Inc. v. Peugeot Motors of Am., Inc., 795 F.2d 329, 338 (4th Cir. 1986) (similar). Moreover, Cutler's assumption is unreasonable on its face because his direct regression model includes numerous different types of opioid medicines that were prescribed for myriad different diagnoses. (Opening Br. at 6). For example, Cutler's direct model implicitly assumes that prescription opioids shipped for short-term use for the treatment of acute pain (which Plaintiffs'

<sup>&</sup>lt;sup>1</sup> Morphine milligram equivalent.

own experts say is appropriate, *see* Expert Report of M. Schumacher, 44) had the exact same impact on mortality as opioids shipped for long-term use for the treatment of chronic pain.

Even ignoring the numerous other methodological flaws in his models, Cutler's direct model shows *at most* that there is positive statistical relationship between *all* shipments of prescription opioids in 400 large counties and *all* opioid mortality in those 400 large counties. But, that is not insightful given that these medicines carry black box warnings about the well-known risks of abuse, addiction, and death. Nor does that average relationship across 400 counties prove anything about Cuyahoga and Summit Counties. This average relationship, therefore, even if it was appropriately measured, does not answer any question that is relevant in this litigation. Accordingly, Cutler's opinions should be excluded.

Second, Plaintiffs are wrong that using a national regression model to estimate an "average" national impact percentage makes Cutler's model "more reliable" than if he had analyzed the relationship in the Track One Counties. (Response at 17). Data that is not representative of the population being studied is not helpful. The additional data related to counties in New York, California, and other states renders Cutler's model less able to estimate any relationship between the alleged misconduct and the alleged harms in the Track One Counties. Indeed, Plaintiffs do not dispute that Cutler admitted his model could not reliably predict the effect of shipments on harms in any particular county. (Opening Br. at 9–10).

Plaintiffs also defend Cutler's reliance on national averages by claiming his model removes the "idiosyncrasies" of a specific county. (Response at 17). But that is exactly what a reliable causation model should address: the actual issue in the case. Here, that issue is the causal relationship, if any, between the alleged Defendant misconduct and the alleged harms suffered by the Track One Counties based on the unique experiences of each of those counties.

Put simply, Plaintiffs admit that Cutler's models fail to account for these idiosyncrasies and thus cannot accurately measure the harms in those Counties allegedly caused by Defendant misconduct. And Cutler does nothing to demonstrate that the national data his direct model relies upon is representative of the Track One Counties. Cutler's opinions must be excluded.

#### B. Cutler's Aggregate Model Is Irrelevant and Unreliable.

Plaintiffs do not dispute that Cutler failed to analyze the harm allegedly caused by any particular shipments or even all shipments by any particular Defendant. (Opening Br. 7-8). Nor can Plaintiffs justify Cutler's reliance on national data by claiming that it fits their "aggregate" proof theory. As an initial matter, an otherwise unreliable model does not become reliable simply because it fits the method of proof adopted by the plaintiff. And while Plaintiffs contend that Courts "routinely admit testimony based on aggregate methodologies" (Response at 19), none of the cases Plaintiffs cite comes close to supporting Cutler's models. Each of those cases involved data related to a single defendant or a single product. See, e.g., Paige v. California, 291 F.3d 1141 (9th Cir. 2002) (allowing aggregation of highway patrol officer exams offered by single defendant); In re Pharm. Indus. Average Wholesale Price Litig., 582 F.3d 156, 198 (1st Cir. 2009) (allowing aggregation of single defendant's pricing practices); Chen-Oster v. Goldman, Sachs & Co., 325 F.R.D. 55, 71 (S.D.N.Y. 2018) (allowing aggregation of data related to single defendant's employment practices); In re Lidoderm Antitrust Litig., 2017 WL 679367, at \*28 (N.D. Cal. Feb. 21, 2017) (allowing aggregation of data related to a single product); In re WorldCom, Inc. Sec. Litig., 2005 WL 375314, at \*7 (S.D.N.Y. Feb. 17, 2005) (allowing aggregation of damages based on financial statements of single defendant). Here, by contrast, Cutler lumps together dozens of defendants, even more products, and 400 counties. Cutler, therefore, cannot reliably opine whether any Defendant's shipments caused any harms in the Track One Counties.

# C. Plaintiffs Failed to Justify the Serious Methodological Flaws in Cutler's Model.

Plaintiffs likewise side-step Cutler's fatal methodological flaws by claiming that each step of Cutler's three-step analysis uses well-recognized methodologies. That is both false and misses the point. As discussed below, Plaintiffs do not identify any precedent for Cutler's methodology in steps one and three. And while his step two regression analyses use some generally accepted techniques, the way Cutler employed them here renders them unreliable for all of the reasons discussed above and in Defendants' Opening Brief. Given these flaws, Plaintiffs do not and cannot identify precedent for combining the results of his three separate steps to draw a causal conclusion about anything, let alone whether the conduct of any Defendant caused the complex, multi-faceted societal harms he attributes to Defendants. Even assuming the methodologies Cutler used in each step were generally accepted (and they are not), the unreliable data he used, flaws in applying those methodologies, and the layered nature of his opinions render his conclusions speculative and unreliable. (Opening Br. at 8).

1. Cutler's Inputs Regarding Alleged Unlawful Promotion and Suspicious Orders are Inherently Unreliable.

With respect to step three of Cutler's analysis, Plaintiffs claim Cutler was justified in using Rosenthal's inputs because "Prof. Rosenthal measured the impact of unlawful promotion on increased *prescriptions* by MMEs - the *same* measurement used by Prof. Cutler when subsequently analyzing the magnitude of prescription opioid *shipments* that caused harm." (Response at 21 (emphasis added)). Of course, converting both prescriptions and shipments to MMEs does not make them the same. Shipments and prescriptions measure two entirely different things and Plaintiffs even acknowledge differences in the data. (*Id.* at 13). But Plaintiffs ignore the larger point: Rosenthal's model is incapable of measuring the number of prescriptions or shipments caused by alleged Manufacturer misconduct because she looks only

at the relationship between all detailing, not alleged Defendant wrongdoing, and prescriptions. (*See* Rosenthal *Daubert*). Because Rosenthal's opinions are unreliable, Cutler's reliance on her "inputs" renders his opinions unreliable and inadmissible too. (Opening Br. at 8–9).

With respect to Distributors, Plaintiffs concede that the "inputs" included in Cutler's original report were provided by counsel and could not be found anywhere in any other expert's report. (Response at 22). In their Response, Plaintiffs claim Cutler "corrected" his model by inserting updated inputs from another expert, McCann, but this new analysis is untimely and has been excluded by the Court. (*See* 8/13/19 SM Cohen Ruling on Mot. to Strike.) Thus, Cutler's opinions as to Distributors are based solely on unsupported inputs from Plaintiffs' counsel, and they are unreliable and inadmissible. (Opening Br. at 8–9).

#### 2. Omitted Variables Render Cutler's Conclusions Unreliable.

Plaintiffs do not dispute that Cutler's models fail to include variables for the introduction of illicit fentanyl into illegal drug markets or "deaths of despair." (Opening Br. at 11–14). However, they claim that the Supreme Court has held that Cutler's omitted variable bias goes to "the model's probativeness rather than its admissibility." (Response at 10) (citing *Bazemore v. Friday*, 478 U.S. 385, 400 (1986) (Brennan, J., concurring in part, joined by all Justices). This is misleading. Plaintiffs omit the word "normally" and the footnote to the very same sentence, in which the Supreme Court made clear that omitted variable bias "may, of course, [make] some regressions so incomplete as to be inadmissible as irrelevant." *Bazemore*, 478 U.S. at n.10. Following *Bazemore*'s direction, other courts have excluded expert opinions due to omitted variable bias. *See e.g.*, *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 253 (6th Cir. 2001) (excluding an expert opinion because it ignored other factors that may have caused the plaintiff's symptoms); *see also* Opening Br. at 11. This Court should do the same.

Plaintiffs try to justify Cutler's failure to include a variable for the introduction of fentanyl based on the assertion that "the emergence of heroin and fentanyl was the *consequence* of prior shipments of prescription opioids." (Response at 11). Yet, Cutler has not done any quantitative analysis to support an opinion that Defendant misconduct fostered transitions to illegal heroin and fentanyl use. (Opening Br. at 13). Indeed, Plaintiffs do not even mention this made-up theory in their Response. Plaintiffs also ignore Cutler's concession that, at most, pre-2010 shipments of prescription opioids are "partially" responsible for "thicker markets for illegal products." (*Id.* (internal quotes omitted)) Plaintiffs have provided no support for Cutler's attempt to blame Defendants for *all* harms from the alleged thickening of the illegal drug market; nor could they, as it is inconsistent with Cutler's own report.

Plaintiffs also ask the Court to overlook Cutler's failure to account for "deaths of despair" because "some of the variables included in the model are *likely* to pick up *some* of these long-term issues." (Response at 11 (emphasis added)). This testimony is no different than Cutler's testimony that he is "explicitly hoping" his model captures these critical variables. (Opening Br. at 14). Plaintiffs do not dispute that "hoping" fails to satisfy Rule 702. (*Id.*)

3. Plaintiffs Cannot Explain Cutler's Use of Mortality as a Proxy for All Harms.

With respect to step two of Cutler's analysis, Plaintiffs claim that Cutler's decision to use mortality as a proxy for five disparate categories of harms is reliable because "[t]he field of health economics also routinely studies how the use of substances . . . are related to personal harms *such* as mortality." (Response at 12 (emphasis added)). That misses the point. Defendants agree that mortality data should be used to analyze trends in mortality. But Cutler used mortality data to predict alleged opioid-related harms that have nothing to do with mortality, such as juvenile court cases, juvenile removals, and addiction treatment. The two papers Plaintiffs cite assess the

relationship between specific substances and mortality, not other types of harm. (*Id.* at 12, n.14) Plaintiffs also cite a book chapter that evaluates mortality and other harms. That source, however, uses data about those other harms (*e.g.*, data on high school and college graduation rates, employment, wages, and homicide and crime rates) to measure those other harms (*e.g.*, impact on educational outcomes, employment, income, and crime, respectively). (*Id.* at 12, n.14). In other words, these sources *do not* support the use of mortality as a proxy for other types of harm.

#### 4. Cutler's Step One Relies on Unreliable Data.

With respect to step one of Cutler's analysis, Plaintiffs claim that Defendants do not "challenge Prof. Cutler's general approach." (Response at 14). To the contrary, Defendants' opening brief made clear that Cutler's entire approach, and step one in particular, is unreliable because he ignores "the facts and circumstances of the Track One Counties," ignores "the multifaceted nature of the crimes, addictions, and child removals, and other harms he analyzes," and, at bottom, constitutes the very "junk justice" and "causation by conjecture" another court has already rejected. (Opening Br. at 8, 18). Because each step in Cutler's analysis—each of which contains multiple sub-steps—relies on fatal methodological flaws, speculative assumptions, and/or unreliable and improperly applied data, when Cutler multiplies the results of his three analyses together, the result is pure speculation that cannot meet the requirements of Rule 702.

Plaintiffs only response is that Cutler "used the same technique for estimating the share of harms attributable to opioids that has been extensively used in scientific [sic] literature for evaluating that question." (Response at 7). The literature cited by Plaintiffs, however, does not support that conclusion. (*Id.* at 7, n.10). Cutler's entire analysis is flawed because he uses national data to estimate county-specific harms. The articles cited by Plaintiffs, on the other hand, use national numbers to estimate national harm. Further, while Cutler uses single, national

data points to estimate twelve years of harm in the Track One Counties, these articles use single data points to estimate harm in a single year.

Cutler also relies on different and less reliable data sources than these articles. For example, Cutler estimates the percent of juvenile removals attributable to opioids for a 12-year period using a single study concerning removals in 2015. (Response at 15). Using a single study of removals in 2015 to estimate 12 years of harm is unreliable enough, but the study does not even quantify removals attributable to opioids. As Plaintiffs concede, it actually only identified the percentage of children taken into custody in 2015 who had "parental drug use as a removal factor" (Response at 15 n.18 (emphasis added))—not as the sole and only cause as Cutler assumes in his analysis. (Opening Br. at 18).

Similarly, Plaintiffs do not dispute that Cutler relies on a single, national survey from 2002 as the source for his estimate of crimes that would not have occurred but for the existence of opioids. (Opening Br. at 17). Instead, they claim that literature cited in footnote 16 of Cutler's Expert Report used the same data sources in the same manner as Cutler. (Response at 14) (citing Cutler Rpt. ¶34 (Dkt. 2000-4/1999-4)). Plaintiffs are wrong. The literature in footnote 16 looked at national trends, but none used the 2002 national survey to identify a percentage of crimes caused *solely* by opioids for a 12-year period in a particular county, like Cutler. Plaintiffs' assertion that Cutler used some "Bellwether-specific data" also is misleading. Cutler multiplied the limited local data he used by percentages he pulled from the 2002 national survey, so the results of his analysis are infected by his unreasonable use of that source.

#### II. <u>CONCLUSION</u>

For the foregoing reasons and the reasons set forth in the Defendants' opening brief, the Court should exclude Cutler's opinions and proposed testimony.

Dated: August 16, 2019

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<sup>&</sup>lt;sup>2</sup> Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and an Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction, they are specially appearing to join this motion, and, thus, they do not waive and expressly preserve their personal jurisdiction challenges.

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### **CERTIFICATE OF SERVICE**

I certify that on August 16, 2019 2019 a copy of the foregoing MANUFACTURER DEFENDANTS' REPLY IN SUPPORT OF MOTION TO EXCLUDE DAVID CUTLER'S OPINIONS AND PROPOSED TESTIMONY was served via email pursuant to the Court's order.

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